In re: Hill et al.

Serial No.: 10/628,057 Filed: July 23, 2003

Page 2 of 12

This listing of the claims will replace all prior versions and listings of the claims in the application:

Listing of the Claims:

1. (Currently Amended) A compound represented by Formula I:

$$R_{6}$$
 R_{5}
 R_{4}
 R_{2}
 R_{13}
 R_{12}
 R_{13}
 R_{12}
 R_{10}
 R_{10}
 R_{10}
 R_{10}
 R_{10}
 R_{10}
 R_{10}
 R_{10}
 R_{10}

or pharmaceutically acceptable salts thereof,

wherein:

the bond represented by the wavy line may be a single or double bond such that when the wavy line is a single bond, R_1 is selected from the group consisting of hydrogen, sulfate and glucuronide or other esters, and when the wavy line is a double bond, R_1 does not exist;

R₂ is lower alkyl;

R₃ is selected from the group consisting of hydrogen, sulfate[[,]] <u>and</u> glucuronide or a conjugate thereof;

 R_4 through R_7 and R_{10} through R_{13} may be the same or different and each represents hydrogen, hydroxy, ketone, lower alkyl, lower alkoxy, halogen, or carbonyl group;

 R_8 and R_9 are independently selected from the group consisting of hydrogen, hydroxy, lower alkyl, lower alkoxy, halogen, and carbonyl groups; and

R₁₄ is selected from the group consisting of hydrogen, sulfate[[,]] <u>and</u> glucuronide or a conjugate thereof;

[[c]]] said compound being present in chemically pure form.

2-3. (Canceled)

In re: Hill et al.

Serial No.: 10/628,057 Filed: July 23, 2003

Page 3 of 12

- 4. (Original) The compound according to Claim 1, wherein said compound is greater than about 95% pure.
- 5. (Original) The compound according to Claim 1, wherein R_2 is C_1 to C_4 alkyl, R_4 - R_{12} are hydrogen and R_{13} is hydrogen or ethynyl.
- 6. (Previously Presented) The compound according to Claim 1, wherein when R_1 is hydrogen, the compound has a β orientation at the C17 position.

7-9. (Canceled)

10. (Currently Amended) A pharmaceutical composition incorporating a compound represented by Formula I:

$$R_{5}$$
 R_{6}
 R_{7}
 R_{7}
 R_{9}
 R_{10}
 R_{10}
 R_{8}
 R_{10}
 R_{10}
 R_{10}
 R_{10}

or pharmaceutically acceptable salts thereof,

wherein:

the bond represented by the wavy line may be a single or double bond such that when the wavy line is a single bond, R_1 is selected from the group consisting of hydrogen, sulfate and glucuronide and other esters, and when the wavy line is a double bond, R_1 does not exist;

R₂ is lower alkyl;

R₃ is selected from the group consisting of hydrogen, sulfate[[,]] and glucuronide or a conjugate thereof;

In re: Hill et al.

Serial No.: 10/628,057 Filed: July 23, 2003

Page 4 of 12

 R_4 through R_7 and R_{10} through R_{13} may be the same or different and each represents hydrogen, hydroxy, ketone, lower alkyl, lower alkoxy, halogen, or carbonyl group;

 R_8 and R_9 are independently selected from the group consisting of hydrogen, hydroxy, lower alkyl, lower alkoxy, halogen, and carbonyl groups; and

R₁₄ is selected from the group consisting of hydrogen, sulfate[[,]] <u>and</u> glucuronide or a conjugate thereof;

said compound being present in chemically pure form.

11-12. (Canceled)

- 13. (Original) The pharmaceutical composition according to Claim 10, wherein said compound is greater than about 95% pure.
- 14. (Original) The pharmaceutical composition according to Claim 10, wherein R₂ is C₁ to C₄ alkyl, R₄-R₁₂ are hydrogen and R₁₃ is hydrogen or ethynyl.
- 15. (Previously Presented) The pharmaceutical composition according to Claim 10, wherein when R₁ is hydrogen, the compound has a ß orientation at the C17 position.
- 16. (Original) The pharmaceutical composition according to Claim 10, wherein said compound is in conjugated form.
- 17. (Original) The pharmaceutical composition according to Claim 10, wherein the composition further comprises at least one additional pharmaceutically active ingredient.
- 18. (Previously Presented) The pharmaceutical composition according to Claim 17, wherein the at least one additional pharmaceutically active ingredient is selected from the group consisting of estrogenic compounds, androgenic compounds, progestin compounds, vasodilation agents, calcium salts, and vitamin D, and mixtures and combinations thereof.

In re: Hill et al.

Serial No.: 10/628,057 Filed: July 23, 2003

Page 5 of 12

19-20. (Canceled)

21. (Currently Amended) A method of treating a subject in need of estrogen therapy, said method comprising administering an effective amount of a compound represented by Formula I:

$$R_{5}$$
 R_{4}
 R_{2}
 R_{13}
 R_{12}
 R_{12}
 R_{13}
 R_{12}
 R_{13}
 R_{14}
 R_{14}
 R_{15}
 R_{16}
 R_{17}
 R_{18}
 R_{19}
 R_{11}
 R_{11}
 R_{12}
 R_{13}
 R_{14}

or pharmaceutically acceptable salts thereof,

wherein:

the bond represented by the wavy line may be a single or double bond such that when the wavy line is a single bond, R₁ is selected from the group consisting of hydrogen, sulfate and glucuronide or other esters, and when the wavy line is a double bond, R₁ does not exist;

R₂ is lower alkyl;

R₃ is selected from the group consisting of hydrogen, sulfate[[,]] and glucuronide or a conjugate thereof;

 R_4 through R_7 and R_{10} through R_{13} may be the same or different and each represents hydrogen, hydroxy, ketone, lower alkyl, lower alkoxy, halogen, or carbonyl group;

 R_8 and R_9 are independently selected from the group consisting of hydrogen, hydroxy, lower alkyl, lower alkoxy, halogen, and carbonyl groups; and

R₁₄ is selected from the group consisting of hydrogen, sulfate[[,]] <u>and</u> glucuronide or a conjugate thereof;

said compound being present in chemically pure form.

22-23. (Canceled)

In re: Hill et al.

Serial No.: 10/628,057 Filed: July 23, 2003

Page 6 of 12

24. (Original) The method according to Claim 21, wherein said compound is

greater than about 95% pure.

25. (Original) The method according to Claim 21, wherein R₂ is C₁ to C₄ alkyl,

 R_4 - R_{12} are hydrogen and R_{13} is hydrogen or ethynyl.

26. (Previously Presented) The method according to Claim 21, wherein when R₁ is

hydrogen, the compound has a ß orientation at the C17 position.

27. (Canceled)

28. (Currently Amended) The method according to Claim 21, wherein said

compound or pharmaceutically acceptable salt thereof is administered as part of a

pharmaceutical composition, said composition further comprising at least one additional

pharmaceutically active ingredient.

29. (Previously Presented) The method according to Claim 28, wherein the at

least one additional pharmaceutically active ingredient is selected from the group consisting

of estrogenic compounds, androgenic compounds, progestin compounds, vasodilation agents,

calcium salts, and vitamin D, and mixtures and combinations thereof.

30-31. (Canceled)

32. (Previously Presented) The method according to Claim 21, wherein the condition

treatable by estrogen therapy is selected from the group consisting of vasomotor symptoms,

atrophic vaginitis, osteoporosis, hypoestrogenism due to hypogonadism, hypoestrogenism

due to castration, hypoestrogenism due to primary ovarian failure, breast cancer in selected

persons with metastatic disease, advanced androgen-dependent carcinoma of the prostate,

abnormal uterine bleeding, and kraurosis vulvae.

In re: Hill et al.

Serial No.: 10/628,057 Filed: July 23, 2003

Page 7 of 12

33. (Previously Presented) A compound represented by the following Formula:

or a pharmaceutically acceptable salt thereof; and said compound has the following physicochemical properties:

having a peak located at about 1.2 ppm on a $^{1}\text{H-NMR}$; and having a peak located at about 45 ppm on a $^{13}\text{C-NMR}$.

34. (Previously Presented) A compound represented by the following Formula:

In re: Hill et al.

Serial No.: 10/628,057 Filed: July 23, 2003

Page 8 of 12

or a pharmaceutically acceptable salt thereof; and said compound has the following physicochemical properties:

having a peak located at about 1.2 ppm on a $^{1}\text{H-NMR}$; and having a peak located at about 45 ppm on a $^{13}\text{C-NMR}$.

35-36. (Canceled)